Medical Device & Diagnostic Industry Magazine | MDDI Article Index

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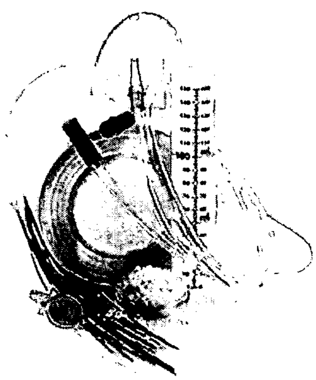

MEDICAL PLASTICS

Coating and Surface Treatment Technologies

Advances in surface modification help manufacturers improve the physical and mechanical characteristics of their devices and enhance biocompatibility.

Jon Katz

The last several years have witnessed an intensification of interest in the discipline known broadly as surface science. Combining aspects of materials analysis, biochemistry, molecular and cell biology, pharmacology, and toxicology, the field is increasing in prominence based on the fact that most biological reactions occur at surfaces. Any fundamental understanding of the biocompatibility of a medical device, for instance, must take into account the basic phenomena of interfaces and surfaces and the properties of proteins and cells at interfaces, as well as the characteristics of local and systemic biological reactions. Principles worked out in surface science laboratories are becoming the basis for ways of improving the function and durability of materials featured in a wide range of medical products.

A variety of methods have been developed to modify the surfaces of polymers or other biomaterials used in the device industry. Examples include conventional coating processes such as spraying or dipping; vacuum deposition techniques; and such surface-modification technologies as diffusion, laser and plasma processes, chemical plating, grafting or bonding, hydrogel encapsulation, and bombardment with high-energy particles. Traditionally, the goal was to achieve improved physical or mechanical properties in a component or device--for example, by adding a nonstick coating to a catheter for easier insertion. Increasingly, however, surface modification also aims at inducing a specific desired bioresponse or inhibiting a potentially adverse reaction.

Several companies offer different surface treatment techniques suitable for device manufacturing with medical-grade plastics. The highlighted companies have contributed information about a particular technique and are not necessarily the only ones providing that type of surface treatment.

Ion-Beam Processing--Spire Corp. (Bedford, MA). Among available surface engineering methods, those employing ionized-particle bombardment have been particularly useful in biomaterial surface modification, in part because of their ability to influence surface properties without altering bulk attributes. Offering reliable, low-temperature processing at reasonable cost, ion beam-based surface treatment employs two primary techniques for treating medical devices: ion implantation and ion beam-assisted deposition (IBAD).

In the ion implantation process, accelerated ions are directed at the surface of a material and create significant changes as a result of interaction with substrate atoms. Since the ions typically penetrate to depths of less than 1 µm and low substrate temperatures are maintained, modifications are confined to the near-surface region. For polymers, proper selection of implantation parameters can produce a cross-linked surface layer with significantly improved hardness and wear resistance. The most common application in this regard is the treatment of artificial joint components made from ultra-high-molecular-weight polyethylene (UHMWPE), with benefits limited only by the shallow depth of implantation. Because ion implantation of silicone rubber or polyurethane has the effect of increasing water wettability and critical surface tension, its use on catheters made from these materials can help reduce biofouling and cumulative thrombus formation.

IBAD is a thin-film vacuum deposition process that combines physical vapor deposition with concurrent ion-beam bombardment. The technique permits the deposition of extremely homogeneous, adherent, low-stress films of virtually any coating material--including metals and ceramics--onto most substrates. Like ion implantation, IBAD is a low-temperature process that is similarly controllable and reproducible. IBAD applications include deposition of infection-resistant coatings or sealant coatings, production of flexible biosensor circuits on polymer substrates, and enhancement of polymethyl methacrylate cement adhesion to UHMWPE orthopedic components.

Light-Activated Surface Modification--BSI Corp. (Eden Prairie, MN). A number of the methods used to treat polymeric devices yield little or no direct substrate bonding and employ coatings that are extremely substrate specific, that tend to abrade or delaminate, or that are unable to bind active biomolecules. An alternative process that can result in durable, cost-effective, generic surface modification is the use of light-activated chemical immobilization of molecules having predefined characteristics. Through the use of photoreactive reagents, the technique can achieve true covalent bonding of a wide variety of molecules to most commonly employed biomaterials.

The process produces extremely thin coatings (typically from 200 to 500 nm) that can be put down with minimal loss in activity of the functional coating molecule. Control of the final coating thickness depends on photoreagent concentration, duration and intensity of photoexposure, coating application procedure, and number of successive coating layers applied. Some of the types of active molecules that can be immobilized for surface treatment purposes are synthetic hydrophilic polymers;

hemocompatibility factors; cell attachments, proteins, and peptides; and synthetic and naturally derived polysaccharides. Material characteristics that can be modified include lubricity, hemocompatibility, antimicrobial properties, cell growth and tissue integration, protein and cell adhesion, and wettability.

Plasma Surface Engineering--Talison Research (Sunnyvale, CA). Adding sufficient additional energy to a gas produces a plasma--a substance sometimes referred to as the "fourth state of matter." In the case of cold gas plasma--the type commonly used for surface modification--the process involves excitation of a gas at reduced pressure by radio-frequency (RF) energy. Plasma surface engineering can be divided into three distinct modalities: ablation, or removal of materials from a surface; alteration, or chemical modification of a surface by activation or grafting of specific functional groups; and accretion, or addition of a new chemical layer (for example, a plasma- deposited film) to a surface.

The effect of a plasma on a polymer surface is determined by the gas chemistry and the process parameters of the reactor system. As with ion-beam systems, plasma treatments impact only a few molecular layers on the surface of a material. The type and degree of modification depend on the composition of the substrate, the process gas employed, the amount of reactive gas flowing through the system, and the level of applied RF power. Typical applications for plasma surface engineering include application of hydrophilic coatings to contact lenses, modification of catheter components to enhance adhesion for bonding or coating, treatment of diagnostic devices for chemical functionalization, and preparation of implant components to receive biocompatible coatings.

Antimicrobial/Antibiotic Coatings--STS Biopolymers, Inc. (Henrietta, NY). Despite the efforts of countless researchers to combat it, device-associated infection remains a major problem in medical care. Infection at indwelling catheters, for example, can result from contaminated disinfectants, from the hands of medical personnel, or as a result of autoinfection from a patient's own microflora. Such infections are not easily treated, since proliferating bacteria on the surface of the catheter can secrete a polysaccharide biofilm or "slime" difficult for systemic antibiotics to penetrate. One way of addressing device- related infection is to incorporate antimicrobial agents directly onto the surface of the device. Silver compounds (silver chloride or silver oxide) are a popular choice for infection-resistant coatings, but many commercially available silver-coated catheters are of marginal effectiveness because the hydrophobic polymer matrix limits the silver ion concentration near the device surface. A process has been developed, however, that incorporates silver compounds in a nonreactive hydrogel polymer system that provides greater aqueous diffusion from the coating and thus a greater concentration of silver ions at and just above the device surface. The coatings can be formulated for short-, intermediate-, or long-term effects; offer controllable lubricity and elution; can be applied inside lumens; and demonstrate superior adhesion, durability, and flexibility. Polymer substrates that can be treated with the technique include polyurethanes, polyolefins, polyesters, PVC, polyamides, polyimides, and silicones.

Thromboresistant (Heparin) Coatings--Baxter Healthcare Corp. (Irvine, CA). Even with the use of systemic anticoagulants, the functioning of devices such as cardiopulmonary bypass circuits, hemodialyzers, ventricular-assist devices, and stents has been associated

with thrombus formation, platelet and leucocyte activation, and other complications related to the deleterious effects of blood/material interactions. Of the various biologically active substances used to improve the hemocompatibility of synthetic surfaces, heparin is perhaps the most promising. In a number of studies, heparin-coated devices have been shown to enhance various aspects of blood compatibility.

Although many techniques have been developed to immobilize heparin onto biomaterial surfaces, one of the most effective is based on the concept of "universal coating," in which the physiochemical properties of heparin are modified by incorporation of a specific binding agent onto the heparin molecules. The resulting heparin coating material has a high affinity to a variety of synthetic surfaces and retains all biological properties of the unmodified heparin. Experiments have shown that the use of immobilized heparin provides greater benefits than does administration of systemic heparin: for example, the availability of heparin-coated bypass circuits has enabled surgeons performing open-heart surgery to decrease levels of systemic heparin, which has helped reduce patient blood loss and transfusion requirements while guarding against thrombus formation.

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